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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,430	01/07/2009	Eric Mangiardi	37621/51001	4712

69821 7590 11/09/2010

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EXAMINER	
STRANSKY, KATRINA M	
ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
11/09/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,430	MANGIARDI ET AL.	
	Examiner	Art Unit	
	KATRINA STRANSKY	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-22 and 24-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-22 and 24-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *July 14, 2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 25 recites the limitation "advancing the release member" in line 13. There is insufficient antecedent basis for this limitation in the claim. It is unclear whether application is referring to advancing the “the first release member” or “the second release member.”

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4, 5, 13-17, 25-28 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Bui et al, US Patent No. 6,413,269 B1.

6. Regarding claim 1, Bui et al disclose a device for stent deployment (11) comprising a stabilizing member comprising a support member (17); an outer tubular member (16) having proximal and distal ends; an inner tubular member (15) having

distal and proximal ends; the distal end of the inner tubular member comprising a tip (15d); the inner tubular member is coupled with the stabilizing member (col. 3, lines 55-65) and at least a portion of the inner tubular member is disposed within the outer tubular member such that the inner tubular member is longitudinally and axially displaceable relative to the outer tubular member (col. 3, lines 55-67). Bui et al disclose a deployment mechanism coupled with the outer tubular mechanism, the deployment mechanism comprising first release member (18) for moving the outer tubular member relative to the inner tubular member from a first position to a second position, and a second release member (19) connected to the first release member for moving the outer tubular member relative to the inner tubular member from the second position to a third position (col. 3, lines 55-67 to col. 4, lines 1-10).

7. Regarding claim 4, Bui et al disclose a safety member (37) for preventing movement of a release member (18) and the outer tubular member (15) toward the support member (17) beyond a predetermined position of the outer tubular member relative to the inner tubular member (col. 5, lines 25-31, the collet 37 locks the inner and outer catheters in relation to each other until longitudinal movement is desired).

8. Regarding claim 5, Bui et al disclose that movement of the first release member from a first position of the outer tubular member relative to the inner tubular member to the predetermined position is adapted to expose at least a portion of the stent (Figure 6, col. 6, lines 29-40).

9. Regarding claim 13, Bui et al disclose a device for stent deployment (11) comprising a stabilizing member comprising a support member (17); an outer tubular

member (16) having proximal and distal ends; an inner tubular member (15) having distal and proximal ends; the distal end of the inner tubular member comprising a tip (15d); the inner tubular member is coupled with the stabilizing member (col. 3, lines 55-65) and at least a portion of the inner tubular member is disposed within the outer tubular member such that the inner tubular member is longitudinally and axially displaceable relative to the outer tubular member (col. 3, lines 55-65), and a stent (10) having a proximal end and a distal end (Figure 2) slidably disposed in the outer tubular member (Figure 1, col. 3, lines 15-20). Bui et al disclose a deployment mechanism coupled with the outer tubular mechanism, the deployment mechanism comprising first release member (18) for moving the outer tubular member relative to the inner tubular member from a first position to a second position, and a second release member (19) connected to the first release member for moving the outer tubular member relative to the inner tubular member from the second position to a third position (col. 3, lines 55-65), where the tip of the inner tubular member engages the proximal end of the stent for advancing the stent toward the distal end of the outer tubular member as the first and second release members move toward the support member (col. 6, lines 22-35).

10. Regarding claim 14, Bui et al disclose that a portion of the stent is exposed outwardly of the distal end of the outer tubular member (col. 6, lines 29-40).

11. Regarding claim 15, Bui et al disclose that the stent is deployed from the distal end of the outer tubular member (col. 6, lines 29-40).

12. Regarding claim 16, Bui et al disclose a safety member (37) for preventing movement of a release member (18) and the outer tubular member (15) toward the

support member (17) beyond a predetermined position of the outer tubular member relative to the inner tubular member (col. 5, lines 25-31, the collet 37 locks the inner and outer catheters in relation to each other until longitudinal movement is desired).

13. Regarding claim 17, Bui et al disclose that movement of the first release member from a first position of the outer tubular member relative to the inner tubular member to the predetermined position is adapted to expose at least a portion of the stent (Figure 6, col. 6, lines 29-40).

14. Regarding claim 25, Bui et al disclose a method for delivering a stent (col. 6, lines 1-5, Figures 4-8) comprising providing a delivery device (11) including a stabilizing member comprising a support member (17); an outer tubular member (16) having proximal and distal ends; an inner tubular member (15) having distal and proximal ends; the distal end of the inner tubular member comprising a tip (15d); the inner tubular member is coupled with the stabilizing member (col. 3, lines 55-65) and at least a portion of the inner tubular member is disposed within the outer tubular member such that the inner tubular member is longitudinally and axially displaceable relative to the outer tubular member (col. 3, lines 55-65), and a deployment mechanism coupled with the outer tubular mechanism, the deployment mechanism comprising first release member (18) for moving the outer tubular member relative to the inner tubular member from a first position to a second position, and a second release member (19) connected to the first release member for moving the outer tubular member relative to the inner tubular member from the second position to a third position (col. 3, lines 55-65), slidably disposing a stent having a proximal end and a distal end in the outer tubular member

(Figures 5 and 6, col. 6, lines 22-35); and advancing the release member and the outer tubular member relative to the inner tubular member in a direction toward the support member (col. 6, lines 22-35); where the tip of the inner tubular member engages the proximal end of the stent for advancing the stent toward the distal end of the outer tubular member as the first and second release members move toward the support member (col. 6, lines 22-35).

15. Regarding claim 26, Bui et al disclose that a portion of the stent is exposed outwardly of the distal end of the outer tubular member (Figure 6, col. 6, lines 29-40).

16. Regarding claim 27, Bui et al disclose that the stent is deployed from the distal end of the outer tubular member (Figure 6, col. 6, lines 29-40).

17. Regarding claim 28, Bui et al disclose preventing movement of a release member (37) and the outer tubular member toward the support member beyond a predetermined position of the outer tubular member relative to the inner tubular member (col. 5, lines 25-32, the collet 37 locks the inner and outer catheters in relation to each other until longitudinal movement is desired).

18. Regarding claim 31, Bui et al disclose that the deployment mechanism is operable without initially disengaging a safety mechanism (col. 3, lines 53-65).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. Claims 6, 8, 18, 20, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bui et al.

21. Regarding claims 6 and 18, Bui et al disclose the claimed invention except for the amount of the stent exposed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to expose about 5 to about 95 percent of the stent since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

22. Regarding claims 8, 20 and 29, Bui et al disclose an elongated viewing device having a proximal and distal end ("endoscope" col. 4, lines 10-25), slidably disposed in the outer tubular member (col. 4, lines 10-25). While Bui et al does not specifically disclose the endoscope extending proximally of the proximal end of the outer tubular member, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the endoscope in a manner such that the proximal end of the viewing device extends outwardly of the proximal end of the outer tubular member in order to allow a user to engage the device with his or her eye, whereas if the proximal end of the endoscope did not extend proximal to the proximal end of the outer tubular member, the endoscope would require additional components for actual use.

23. Claims 7, 9, 10, 12, 19, 21, 22, 24, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bui et al in view of Derus et al, US Publication No. 2002/0183827 (hereinafter referred to as Derus).

24. Regarding claims 7 and 19, Bui et al lack the teaching that the safety member comprises a removable tab disposed between the support member and the outer tubular member. However, Derus teaches a safety member comprising a removable tab (56, Figure 6 shows the tab disposed between the distal end of the outer tubular member and the stabilizing member). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the safety member of Bui et al with the removable tab as taught by Derus in order to maintain the outer tube in position until deployment of the stent (Derus, paragraph 0043).

25. Regarding claims 9, 21 and 30, Bui et al disclose the claimed invention except for means for releasably securing the viewing device. However, Derus teaches means for releasably securing the viewing device (106). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the support of Bui et al with the securing means as taught by Derus in order to releasably secure an endoscope in order to view the stent and determine proper placement of the stent (Derus, paragraph 0053).

26. Regarding claims 10 and 22, Bui et al disclose the claimed invention except for the viewing device securing means is associated with the stabilizing member. However, Derus teaches that the securing means is associated with the stabilizing member (see Figure 5b). It would have been obvious to one having ordinary skill in the art at the time

the invention was made to make the support of Bui et al with the securing means as taught by Derus in order to releasably secure an endoscope in order to view the stent and determine proper placement of the stent (Derus, paragraph 0053).

27. Regarding claims 12 and 24, Bui et al and Derus disclose the claimed invention except for threadingly attached the clamp 106. It would have been an obvious matter of design choice to use a threaded clamp, since applicant has not disclosed that threading solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with any sort of clamp, such as a press-fit clamp or a snap-fit clamp.

Response to Arguments

28. Applicant's arguments with respect to claims 1-5, 7, 13-22 and 24-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent Nos. 5,591,172; 6,383,211 B1; 6,093,194; 6,143,021 and US Publication No. 2002/0151967 A1 are cited to show stent delivery systems having multiple deployment mechanisms.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATRINA STRANSKY whose telephone number is

(571) 270-3843. The examiner can normally be reached on Monday thru Friday, 8:00 am to 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KS/
Examiner, Art Unit 3734

/TODD E. MANAHAN/
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